DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY - 2 2000

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The Honorable Dan Burton
House of Representatives
Washington, D.C. 20515-1406

Dear Mr. Burton:

Thank you for your letter of March 20, 2000, regarding the Administration's *Egg Safety Action Plan*, "Egg Safety from Production to Consumption: An Action Plan to Eliminate Salmonella Enteritidis Illness Due to Eggs." As you know the Department of Health and Human Services' Food and Drug Administration (FDA or the Agency) and the United States (U.S.) Department of Agriculture's Food Safety and Inspection Service (FSIS) are the agencies implementing this plan. You asked five questions pertaining to FDA's portion of the plan. We will address the questions in the order in which they appear in your letter.

1) What would be the economic impact on the egg industry if all producers were to adopt the process of in-shell pasteurization?

In the *Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels* (Federal Register Vol. 64, No. 128, July 6, 1999), the Agency estimates the cost to pasteurize all 47 billion shell eggs sold each year to be approximately $1.2 billion per year. In developing the *Egg Safety Action Plan*, FDA was aware that in-shell pasteurization is currently very costly and understands that most producers, at least initially, would seek to be covered by Strategy I- on farm preventive controls vs. Strategy II- employing a "kill step" such as in-shell pasteurization. By including this second option, however, the regulations would encompass new technologies as they became established scientifically and feasible economically. Notwithstanding costs, the "kill step" technology does exist and is being applied in targeted markets in this country. We believe the technology will become more cost-effective with an

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increased market share and development of more efficient equipment and processes to pasteurize shell eggs.

2) In the first objective of the Egg Safety Action Plan, a strong dependence is placed on testing the environment of the chicken and then diverting all the eggs, if a positive environmental sample is found, to an egg-breaking plant for pasteurization. I understand the incidence of SE (Salmonella Enteritidis) in eggs is one in twenty thousand eggs. It seems that the economic impact on any egg producer who discovers a positive environmental sample could be severe with the pasteurization of thousands of perfectly wholesome eggs. Has the Department done an economic impact analysis on the level of testing and the diversion of product it is proposing for the egg industry?

The regulatory impact (economic) analysis is currently underway. The goal of the *Egg Safety Action Plan* is to reduce SE illness associated with eggs by 50% by 2005 and ultimately eliminate eggs as a source of SE by 2010. The steps outlined in the Plan are critical to meeting these public health goals.

Finally, the Agency is considering diversion of eggs as one means to reduce the potential for contaminated eggs from reaching U.S. consumers and causing illness. Diversion and its cost and benefits will be taken into account in the regulatory impact analysis.

3) Did the Egg Safety Action Plan use the most current Center for Disease Control (CDC) data or was it data taken from 1990-1994? If so, why?

The *Egg Safety Action Plan* provides a roadmap to guide the Federal agencies in the consistent application of standards in implementing SE reduction strategies. The *Egg Safety Action Plan* included published data on SE illnesses and outbreaks and uses CDC's 1998 outbreak, illness and isolate data for comparison purposes. Nonetheless, FDA will utilize the most up-to-date information, data and reports in crafting the proposed rules.

4) What plans do the Department of Health and Human Services have for ensuring consistent enforcement among the 50 State agencies?

FDA will assure that the individual States consistently enforce uniform standards through education and training, which will

include inspection force training, on-farm and packer/processor training, a training certification program, compliance guides, and laboratory standards and criteria. In addition, the Agency is considering the possibility of national third party monitoring for compliance. We are also considering a collaborative Federal/State/industry training program to achieve consistent application of standards nationwide.

5) The Food and Drug Administration's proposed safe-handling label, when compared with the meat and poultry safe handling label, implies that eggs are less safe. Is that the case? If so, why?

The proposed safe handling statement is not intended to imply that eggs are less safe than meat and poultry. The purpose of the proposed safe handling statement for eggs is to give consumers ways to reduce their risk, without having to avoid the product. We tentatively concluded that to adequately inform consumers of ways to reduce their risk, there was a need to include information on why there was a risk associated with consumption of raw or improperly cooked eggs. We received several comments on the proposed safe handling statement that are similar to yours and intend to address these comments when we take final action in this rulemaking.

We consider all of the issues and concerns mentioned in your letter as important. The *Egg Safety Action Plan* implementation will consider these matters as we develop our proposed regulations for on-farm and final regulations for retail national standards for shell egg producers. Likewise, FSIS is crafting companion national standards covering packers/processors. The proposed rules will be subject to public review and comment and are expected to be published in the fall. Public meetings were held on March 30, 2000, in Ohio and April 6, 2000, in California, to discuss what might be included in proposed standards.

The information obtained at the public meetings and during the comment period following the meetings will be carefully considered as the proposed regulations are crafted. The meetings have assisted FDA and FSIS in obtaining information on what technology and procedures are available and practical for reducing or eliminating the risk of SE in eggs. Likewise, we appreciate your continued participation in this process.

Currently we are reviewing the comments we have received on the proposed labeling and refrigeration rules. Your comments will be considered along with all other comments received in response to the proposed rules in developing practical and effective public health measures to reduce illnesses associated with shell eggs. As noted above, FDA plans to publish final rules on labeling and refrigeration later this year.

We appreciate your concerns and look forward to working with industry, States, consumers, and our Federal counterparts in developing nationwide consistent standards to reduce SE illnesses associated with eggs. If you have further questions, please let us know.

Sincerely,

for Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: Dockets Management Branch

DAN BURTON
8TH DISTRICT, INDIANA

COMMITTEES:
GOVERNMENT REFORM AND OVERSIGHT
CHAIRMAN

INTERNATIONAL RELATIONS

SUBCOMMITTEES:
INTERNATIONAL OPERATIONS AND HUMAN RIGHTS
WESTERN HEMISPHERE

WASHINGTON OFFICE:
2185 RAYBURN BUILDING
WASHINGTON, DC 20515-1406
TELEPHONE: (202) 225-2276

DISTRICT OFFICES:
8900 KEYSTONE AT THE CROSSING
SUITE 1050
INDIANAPOLIS, IN 46240
TELEPHONE: (317) 848-0201
TOLL-FREE: (800) 382-6020

435 EAST MAIN STREET
SUITE J-3
GREENWOOD, IN 46142
TELEPHONE: (317) 882-3640
TOLL-FREE: (800) 678-3642

WORLDWIDE WEB PAGE:
http://www.house.gov/burton/

Congress of the United States
House of Representatives
Washington, DC 20515-1406

March 20, 2000

The Honorable Donna E. Shalala
Secretary of Health and Human Services
Room 615F
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Madam Secretary:

The safety and wholesomeness of our Nation's food supply is a high priority that demands the appropriate resources and expertise. The President's Food Safety Initiative demonstrates Federal attentiveness to this issue. However, the Egg Safety Action Plan has raised some concerns among my Indiana constituents. Therefore, I would appreciate your response to the following questions:

1). What would be the economic impact on the egg industry if all producers were to adopt the process of in-shell pasteurization?

2). In the first objective of the Egg Safety Action Plan, a strong dependence is placed on testing the environment of the chicken and then diverting all the eggs, if a positive environmental sample is found, to an egg-breaking plant for pasteurization. I understand that the incidence of SE (Salmonella enteritidis) in eggs is one in twenty thousand eggs. It seems that the economic impact on any egg producer who discovers a positive environmental sample could be severe with the pasteurization of thousands of perfectly wholesome eggs. Has the Department done an economic impact analysis on the level of testing and the diversion of product it is proposing for the egg industry?

3). Did the Egg Safety Action Plan use the most current Center for Disease Control data or was it data taken from 1990-1994? If so, why?

4). What plans do the Department of Health and Human Services have for ensuring consistent enforcement among the 50 State agencies?

5). The Food and Drug Administration's proposed safe-handling label, when compared with the meat and poultry safe handling label, implies that eggs are less safe. Is that the case? If so, why?

This issue is very important to farmers and consumers, and I thank you in advance for your timely and personal attention to this matter.

Sincerely,

Dan Burton

Dan Burton
Member of Congress

No 00-2132

Secretary's Correspondence

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

From:	**Dan Burton**	*OS#:*	**032820000030**
Organization:	**Representative - Indiana**	*Date on Letter:*	**3/20/00**
City/State:	**Washington DC**	*Date Received:*	**3/28/00**
On Behalf Of:		*Type:*	**Congressional**
Subject:	**Seeks response to series of questions regarding the Egg Safety Action Plan. The incidence of Salmonella enteritidis in Eggs.**		

Assigned to:	**FDA**	*Dep.ES:*	**Jacquelyn White**
PC:	**Jonathan Friebert**	*Date Assigned:*	**3/28/00**
Action Required:	**Sec Sig**	*Date Reassigned:*	
		Reply Due Date:	**4/11/00**

Info Copies To:	**ASL; ASMB; ASPE; CDC; DXS; ESS; Friebert, Jonathan; NIH; OPHS; SEC; Varnado, Martina**		
Interim (Y/N):	**No**	*Date Interim Sent:*	
Comments:			
File Index:	**PO-4-6**	*CCC:*	**Ottis Hamilton**

No 00-2132